

## Food and Drug Administration, HHS

## § 1271.25

you are not required to update your listing.

(ii) If a change described in §1271.25(c) has occurred, you must update your HCT/P listing with the new information:

(a) At the time of the change, or

(b) Each June or December, whichever month occurs first after the change.

### § 1271.22 How and where do I register and submit an HCT/P list?

(a) You must use Form FDA 3356 for:

(i) Establishment registration,

(ii) HCT/P listings, and

(iii) Updates of registration and HCT/P listing.

(b) You may obtain Form FDA 3356:

(i) By writing to the Center for Biologics Evaluation and Research (HFM-305), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, Attention: Tissue Establishment Registration Coordinator;

(ii) By contacting any Food and Drug Administration district office;

(iii) By calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800;

(iv) By calling the Fax Information System at 1-888-CBER-FAX or 301-827-3844; or

(v) By connecting to <http://forms.psc.gov/forms/FDA/fda.html> on the Internet.

(c)(i) You may submit Form FDA 3356 to the Center for Biologics Evaluation and Research (HFM-305), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, Attention: Tissue Establishment Registration Coordinator; or

(ii) You may submit Form FDA 3356 electronically in accordance with the instructions provided with the form.

EFFECTIVE DATE NOTE: At 69 FR 68681, Nov. 24, 2004, §1271.22 was revised, effective May 25, 2005. For the convenience of the user, the revised text is set forth as follows:

### § 1271.22 How and where do I register and submit an HCT/P list?

(a) You must use Form FDA 3356 for:

(1) Establishment registration,

(2) HCT/P listings, and

(3) Updates of registration and HCT/P listing.

(b) You may obtain Form FDA 3356:

(1) By writing to the Center for Biologics Evaluation and Research (HFM-775), Food

and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, Attention: Tissue Establishment Registration Coordinator;

(2) By contacting any Food and Drug Administration district office;

(3) By calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800; or

(4) By connecting to <http://www.fda.gov/opacom/morechoices/fdaforms/cber.html> on the Internet.

(c)(1) You may submit Form FDA 3356 to the Center for Biologics Evaluation and Research (HFM-775), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, Attention: Tissue Establishment Registration Coordinator; or

(2) You may submit Form FDA 3356 electronically through a secure web server at <http://www.fda.gov/cber/tissue/tisreg.htm>.

### § 1271.25 What information is required for establishment registration and HCT/P listing?

(a) Your establishment registration Form FDA 3356 must include:

(1) The legal name(s) of the establishment;

(2) Each location, including the street address of the establishment and the postal service zip code;

(3) The name, address, and title of the reporting official; and

(4) A dated signature by the reporting official affirming that all information contained in the establishment registration and HCT/P listing form is true and accurate, to the best of his or her knowledge.

(b) Your HCT/P listing must include all HCT/P's (including the established name and the proprietary name) that you recover, process, store, label, package, distribute, or for which you perform donor screening or testing. You must also state whether each HCT/P meets the criteria set out in §1271.10.

(c) Your HCT/P listing update must include:

(1) A list of each HCT/P that you have begun recovering, processing, storing, labeling, packaging, distributing, or for which you have begun donor screening or testing, that has not been included in any list previously submitted. You must provide all of the information required by §1271.25(b) for each new HCT/P.

(2) A list of each HCT/P formerly listed in accordance with §1271.21(a) for which you have discontinued recovery,